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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/294,663	04/19/99	GRANADOS	R BTI-39-CIP

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EXAMINER

IBRAHIM, M

ART UNIT	PAPER NUMBER
1649	9

DATE MAILED: 02/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/294,663

Applicant(s)
Granados et al

Examiner
Medina A. Ibrahim

Group Art Unit
1638



☒ Responsive to communication(s) filed on Nov 26, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-3 and 5-19 is/are pending in the application.

Of the above, claim(s) 2, 8, and 11-19 is/are withdrawn from consideration.

☒ Claim(s) 3, 5, 7, and 10 is/are allowed.

☒ Claim(s) 1, 6, and 9 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1638.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3 and 5-19 remain pending.

Claims 1, 3, 5-7, 9-10 remain under examination . Claim 4 is canceled.

Restriction/election

1. Applicant's election with traverse of Group I and plant species in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the examiner improperly restricted between claims directed to related inventions. Applicants argue that the examiner did not make a prima facie case to support the two criteria for restriction requirement (page 4, 1st and 2nd paragraphs). The applicants further argue that even if some of the inventions would be classified separately, a thorough search of the prior art for any of the inventions would include the classes and subclasses of the other invention and would not create a burden on the examiner .

These arguments have been considered and not found persuasive because of the following reasons: The claim that is directed to a DNA sequence encoding an IIM protein is patentably distinct from each of the claims directed to a DNA encoding antibody to IIM, or a DNA encoding

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a fusion protein comprising IIM, for example. The examiner did not restrict between claims directed to indistinct inventions. The six groups were found distinct because that they are drawn to six different modes of operation involving biochemically and physiologically distinct products as stated previously. Furthermore, a transformed plant species is not obvious over each of transformed virus, a transformed microbe, or a transformed animal, for example. Each transformed product and process of making it would require a separate search. There is no reason to expect the searches to be coextensive. Accordingly, serious search burden exists.

The requirement is still deemed proper and is therefore made FINAL.

Withdrawn Objections and Rejections

Objections and Rejections Under 35 USC 101, 112 and 103

Objections to the specification and to claim 1, grounds of rejections under 35 U.S.C. 112, second paragraph to claims 1, 3, 5 and 9-10, and the rejection to claim under U.S.C. 101 in Paper No. 5 are withdrawn in view of Applicant's amendments.

The rejection under 35 USC 103 to claims 1, 3, 5, 9-10 as being unpatentable over Kramer et al (US 5, 866, 788) over Wang et al has been withdrawn in view of applicants' argument that the authorship of the Wang et al reference is identical to the inventorship of the present application.

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Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 6, and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims are broadly drawn to a transformed plant comprising a gene operably linked to a control sequence in an expression vector encoding an invertebrate intestinal mucin (IIM) protein, and a method for producing an IIM protein or peptide by transforming a host cell with an expression vector comprising a promoter, glutathione- S- transferase gene , and a nucleotide sequence encoding a predetermined protein or peptide of an IIM protein, culturing and lysing said host cell, and recovering said IIM protein. In contrast, the specification provides guidance only for a transformed plant expressing the isolated cDNA sequence of SEQ ID NO:1 or 2 encoding *Trichoplusia ni* IIM protein with an amino acid sequence of SEQ ID NO: 3 or 4, and the in vitro production of *Trichoplusia ni* IIM protein by using baculovirus expression vector to infect insect cells. No guidance has been presented for the isolation and expression of other invertebrate intestinal genes encoding IIM proteins with chitin binding activity and their potential as an insecticide in the exemplified or non-exemplified host cells.

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Furthermore, genes encoding proteins thought to be directly involved in disease resistance may be ineffective in conferring disease resistance, following their expression in transgenic plants (see, e.g., Linthorst et al, page 285, Abstract). Expression of insecticidal proteins in transformed plants may fail to confer protection (see, e.g., Dandekar et al, page 151, Abstract).

Given the claim breadth, unpredictability and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to isolate a multitude of genes from a multitude of invertebrate animals' intestinal midgut including a multitude of insects' or non insects' intestinal midgut encoding a multitude of IIM proteins in plant cells, and to evaluate their ability to control insect damage in plants. Therefore, the instant invention could not be practiced without undue experimentation.

Claims 1, 6 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are broadly drawn to a multitude of genes from a multitude of invertebrates' intestinal midgut including a multitude of insects' or non-insects' intestinal midgut in a multitude of transformation vectors with a multitude of promoters encoding a multitude of IIM proteins in plant cells. In contrast, the specification only provides guidance for a cDNA sequence from *Trichoplusia ni* in a vector encoding *Trichoplusia ni* IIM protein.

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Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the invention as broadly claimed.

See Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene or a promoter is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g a DNA sequence) and page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

See *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is indefinite in its recitation of the phrase "expression vector further comprises a transfer molecule", which is confusing because the nucleic acid vector can not comprise the subsequently recited protein. An insertion of --- gene encoding the --- after "a" would obviate the rejection.

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Claims 1, 3, 5-7, and 9-10 are deemed free of the prior arts, in view of the failure of the prior art to teach or suggest an isolated IIM gene.

Claims 3, 5, 7, and 10 are allowed.

The following Examiner's Amendment^s, proposed on 14 January 2000, were not approved by Applicants' representative.

IN THE CLAIMS:

Cancel claims 2, 8, and 11-19.

In claim 1, lines 3-4, replace "an Invertebrate" with --- a *Trichoplusia ni* ---.

In claim 6, lines 1 and 4, insert ---*Trichoplusia ni*--- before "IIM".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The examiner can normally be reached on Monday through Friday from 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

February 3, 2000
mai

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

David T. Fox